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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,985	SHORT, JAY M.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-31,33-41,44,46 and 48-66* is/are pending in the application.

4a) Of the above claim(s) *15-18 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14,19-31,33-41,44,46,48-58 and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/17/05,10/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 8-31, 33-41, 44, 46, 48-66 are pending.

Applicant's amendment of claims 8-9, 12-14, 19-20, 22-24, 26, 29-30, 34-35, 38-41, 44, 46, 49, cancellation of claims 42-43, 45 and 47, addition of claims 50-66, and amendments to the specification in a communication filed on 10/20/2005 are acknowledged.

Applicants request rejoinder of method claims after the elected product claims have been found to be allowable. Since the elected product claims are not allowable at this time, the restriction previously applied is maintained.

As indicated in the Non Final Action mailed on 5/18/2005, claims 15-18 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to an invention non-elected without traverse in a communication filed on 2/24/2005. New claim 59 is directed to a non-elected invention and is withdrawn from consideration by the Examiner. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 8-14, 19-31, 33-41, 44, 46, 48-58, 60-66 are under consideration and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 6/17/2005 and 10/20/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the Examiner.

Priority

2. As previously indicated, a sequence search showed that SEQ ID NO: 2, as disclosed in the sequence listing, was first disclosed in U.S. Application No. 09/259,214 filed on 03/01/1999. Applicants argue that SEQ ID NO: 2 was first disclosed in Figure 1A and 1B of U.S. Patent No. 5876997. Thus, Applicants submit that the claimed invention can properly claim priority to parent application 08/910798, filed on 8/13/1997.

3. It is noted that while it appears that Figure 1A and 1B disclose a polypeptide having the same number of amino acids as that of the polypeptide of SEQ ID NO: 2, without a sequence alignment, the Examiner cannot rely solely on visual inspection of those figures to determine whether the entire polypeptide of SEQ ID NO: 2 is shown in Figure 1A and 1B. SEQ ID NO: 2 is 440 amino acids long and while the Examiner can verify some fragments of the sequence in question, visual inspection of the entire sequence to corroborate whether SEQ ID NO: 2 as disclosed in the instant application is that shown in Figure 1A and 1B is not possible. Upon performing an alignment of SEQ ID NO: 2 of the instant application and the sequence disclosed in parent application 08/910798 as SEQ ID NO: 2, it was found that what has been disclosed as SEQ ID NO: 2 in the priority application is not the same as SEQ ID NO: 2 of the instant application. Thus, for the reasons previously stated, the priority date granted is 03/01/1999.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 40, 52 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 40, 52 and 57 are indefinite in the recitation of "wherein the polypeptide comprising a signal peptide ..is secreted ..." as there is no antecedent basis for a polypeptide comprising a signal peptide. It is suggested the term be amended to recite "wherein the phytase comprises a signal peptide... and is secreted....". For examination purposes, the suggested language will be used. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 29, 34 remain rejected and new claims 60-63, 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection which is now applied to new claims 60-63, 65 for the reasons of record and those set forth below.

9. Applicants argue that support for claims 9 and 26 is found in page 16, lines 6-17. Furthermore, Applicants submit that these claims have been amended to expressly use the term "*in vitro* transcription" as shown in the specification. With regard to claims reciting specific host cells, Applicants submit that the specification supports the use of host cells known in the art, as stated in page 58, lines 16-21. In addition, Applicants argue that the description does not have to explicitly disclose every single nuance in the claims and does not have to use the same words to be sufficient. According to Applicants, the specification supports claims encompassing the use of any yeast host cell and any gram positive bacteria. With regard to claims reciting specific cloning vehicles, Applicants submit that the specification indicates

that the polynucleotide of the invention can be used in any expression vector. Therefore, it is Applicant's contention that there is support for bacteriophages.

10. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 29, 34 or to avoid the rejection of claims 60-63. Claim 29 is directed to the feed of claim 28 wherein the yeast cell is a *Saccharomyces* sp. Claim 34 is directed in part to the feed of claim 31 wherein the gram positive bacteria is a *Bacillus* sp. Claims 60-63 are directed to the feed of claims 28 or 31 wherein the host cells are specific yeast cells or specific gram positive bacterial cells. Claim 65 is directed to the feed of claim 38 wherein the cloning vehicle comprises a bacteriophage. The Examiner acknowledges that (1) the specification discloses that the phytase can be recombinantly made in host cells commonly used in the art, (2) the specification discloses that the polynucleotide of the invention can be inserted in a variety of expression vectors, and (3) the specification does not have to disclose every nuance in the claims or use the exact same words as those used in the claims. However, it is noted that a genus of host cells or a genus of cloning vehicles may not provide support to a subgenus of host cells or cloning vehicles even though there is a disclosed species within the subgenus. See *In re Smith* 173 USPQ 679 (CCPA 1972), *In re Ruschig* 371 F.2d 990, 154 USPQ 118 (CCPA 1967), *Purdue Pharma L.P. v Faulding Inc.*, 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000). While the specification refers to a genus of yeast host cells, a genus of gram positive bacteria, and a genus of cloning vehicles, there is no indication in the specification or the claims as originally filed that the specific species/subgenus recited in the claims were within the scope of the invention as conceived by Applicant at the time the application was filed. Therefore, as previously indicated, Applicants are required to cancel the new matter in response to this Office Action.

11. Claims 8-11, 13, 19, 23-31, 33-41, 44, 46, 48 remain rejected and new claims 50-53, 56-57, 60-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005 and is now applied to new claims 50-53, 56-57, 60-65 for the reasons of record and those set forth below.

13. Applicants argue that what is conventional or well known in the art need not be disclosed in detail. Specifically, Applicants submit that the *E. coli* phytases required in the feeds of the invention are well known both in sequence and function. Similarly, Applicants state that the second component of the claimed invention –animal feeds- are also well known.

14. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 8-11, 13, 19, 23-31, 33-41, 44, 46, 48 or avoid the rejection of new claims 50-53, 56-57, 60-65. Claims 8-11, 13, 19, 23-31, 33-41, 44, 46, 48 have been amended such that the feed/food composition claimed requires a phytase encoded by a nucleic acid derived from an *E. coli*. While the prior art discloses two *E. coli* phytases (Greiner et al., Arch. Biochem. Biophys. 303:107-113, 1993), the claims encompass not only any phytase naturally found in *E. coli* but an infinite number of variants of phytases naturally found in *E. coli*. It is noted that the term "derived from an *E. coli*" does not limit the genus of nucleic acids to naturally-occurring nucleic acids in view of the fact that the term "derived" does not exclude mutants. The specification fails to disclose which are the structural elements in the polypeptide of SEQ ID NO: 2 which are found in any *E. coli* phytase nor does it provide the structural elements required in any variant of any *E. coli* phytase such that it retains phytase activity. Therefore, contrary to Applicant's assertion, the claimed invention requires phytases which are not well known as they have not been structurally described.

15. Claims 8-11, 13, 19, 23-31, 33-41, 44, 46, 48 remain rejected and new claims 50-53, 56-57, 60-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for food/feed compositions comprising the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for food/feed compositions comprising any phytase encoded by a nucleic acid which is derived from *E. coli*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

16. This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005 and is now applied to new claims 50-53, 56-57, 60-65 for the reasons of record and those set forth below.

17. Applicants argue that the feeds of the invention encompass the use of known E. coli phytases and that animal feeds are also well known in the art. Applicants also argue that a patent need not teach, and preferably omits, what is well known in the art. Since both *E. coli* phytases and animal feeds are well known in the art, applicants submit that the specification provides enablement for the full scope of the claimed invention.

18. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 8-11, 13, 19, 23-31, 33-41, 44, 46, 48 or avoid the rejection of new claims 50-53, 56-57, 60-65. As indicated above, claims 8-11, 13, 19, 23-31, 33-41, 44, 46, 48 are now directed to feed/food compositions which require a phytase encoded by a nucleic acid derived from an *E. coli*. The claims encompass not only any phytase naturally found in *E. coli* but an infinite number of variants of phytases naturally found in *E. coli*. It is noted that the term "derived from an *E. coli*" does not limit the genus of nucleic acids to naturally-occurring nucleic acids in view of the fact that the term "derived" does not exclude variants of an *E. coli* nucleic acid encoding a phytase. It is reiterated herein that the specification fails to disclose which are the structural elements in the polypeptide of SEQ ID NO: 2 which are found in any *E. coli* phytase and it does provide the structural elements required in any variant

of any *E. coli* phytase such that it retains phytase activity. Furthermore, there is no teaching as to the general tolerance of phytases to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (Introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by experiments where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing *de novo* stable proteins with specific functions. The teachings of Branden et al. are further supported by the teachings of Witkowski et al. (Biochemistry 38:11643-11650, 1999) and Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) previously discussed, where it is shown that even small amino acid changes result in enzymatic activity changes.

While methods of generating or isolating variants of a polynucleotide were known in the art at the time of the invention, it was not routine in the art to screen by a trial and error process for any number of variants of a nucleic acid isolated from *E. coli* to determine which ones encode a phytase. Furthermore, it is not routine in the art to isolate/create any polynucleotide encoding a protein with the activity recited without any knowledge as to the structural features which would correlate with that activity. In the absence of (1) a rational and predictable scheme for modifying any nucleotide in the nucleic acid of SEQ ID NO: 1 such that the resulting variant would encode a protein which retains phytase activity, and/or (2) a correlation between structure and phytase activity, one of skill in the art would have to test an

essentially infinite number of polynucleotides to determine which ones encode proteins having phytase activity.

Therefore, taking into consideration the scope of the claims, the lack of guidance, the amount of information provided, the lack of knowledge about a correlation between structure and function, and the high degree of unpredictability of the prior art in regard to structural changes and their effect on function, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to practice the claimed invention. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

19. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20. Claims 8-13, 19, 23, 26-31, 33-40 were rejected under 35 U.S.C. 102(b) as being anticipated by Apajalahti et al. (GB 2316082 A, published 2/18/1998). This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

21. Applicants argue that SEQ ID NO: 2 can properly claim priority to parent application 08/910798, filed on 8/13/1997. Thus, the instant reference is not prior art to the claimed invention.

22. Applicant's arguments have been fully considered. For the reasons set forth above, the claimed priority has not been granted. However, in view of the fact that the claims now require a phytase encoded by a nucleic acid derived from *E. coli* and Apajalahti et al. teach a food and feed composition comprising a *B. subtilis* phytase, the teachings of the instant reference no longer anticipate the claims as amended nor do they anticipate new claims 50-66. Thus, this rejection is hereby withdrawn.

23. Claims 8-13, 19, 23-24, 26-31, 33-40 were rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

24. Applicants argue that after entry of the amendment filed on 10/20/2005, the claims are now directed to feed/food compositions comprising a phytase encoded by a nucleic acid derived from an *E. coli*. Thus, Applicants submit that since Cheng et al. do not teach isolating or using a phytase from an *E. coli*, the instant reference no longer anticipates the claimed invention.

25. Applicant's arguments have been fully considered. In view of the fact that the claims now require a phytase encoded by a nucleic acid derived from *E. coli* and Cheng et al. teach a food and feed composition comprising a *Selenomonas ruminatum* phytase, the teachings of the instant reference no longer anticipate the claims as amended nor do they anticipate new claims 50-66. Thus, this rejection is hereby withdrawn.

Claim Rejections - 35 USC § 103

26. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

27. Claims 24-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Apajalahti et al. (GB 2316082 A, published 2/18/1998) in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

28. Applicants argue that SEQ ID NO: 2 can properly claim priority to parent application 08/910798, filed on 8/13/1997. Thus, Apajalahti et al. is not prior art to the claimed invention.

29. Applicant's arguments have been fully considered. As indicated above, the claimed priority has not been granted. However, since neither Cheng et al. nor Apajalahti et al. alone or in combination teach

or suggest a food/feed composition comprising a phytase derived from *E. coli*, this rejection is hereby withdrawn.

30. Claim 25 was rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

31. In view of the fact that claim 25 now requires a phytase derived from *E. coli*, and Cheng et al. does not teach a feed/food composition comprising an *E. coli* phytase, this rejection is hereby withdrawn.

32. Claims 8-13, 19, 24-31, 33-40, 50-53, 56-57, 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS) in view of Greiner et al. (Archives of Biochemistry and Biophysics 303(1):107-113, 1993; cited in the IDS). This rejection was previously applied to now canceled claims 42-43, 45 and 47. This rejection is necessitated by amendment and is now applied to claims 8-13, 19, 24-31, 33-40, 50-53, 56-57, 60-65 for the reasons of record and those set forth below.

33. With regard to claims 42-43, 45 and 47, Applicants argue that Greiner does not teach food/feeds comprising a phytase and that Chen et al. do not teach an *E. coli* phytase. Also, Applicants submit that neither reference suggest or teach using any *E. coli* phytase in any feed/food composition. Therefore, a prima facie case of obviousness has not been made.

34. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection of claims 8-13, 19, 24-31, 33-40, 50-53, 56-57, 60-65.

Amended claims 8-13, 19, 26-31, 33-40, 50-52, 56, 60-65 of the instant application are directed in part to a feed/food composition comprising a phytase encoded by a nucleic acid derived from *E. coli*, wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and

wherein the phytase is secreted by the cell. Since how the phytase is made does not affect the structure or function of the phytase, no consideration has been placed on limitations regarding the method of making the phytase. Claim 23 is directed in part to a food composition for an animal comprising a phytase encoded by a nucleic acid derived from E. coli wherein said composition is a liquid formulation or comprises a liquid formulation. Claim 24 is directed to a drinkable foodstuff comprising a phytase encoded by a nucleic acid derived from E. coli. Claim 25 is directed in part to the drinkable foodstuff of claim 24 wherein the foodstuff further comprises juice. Claims 53 and 57 are directed to a food composition/drinkable foodstuff comprising a phytase encoded by a nucleic acid derived from E. coli wherein the phytase lacks a signal peptide.

Cheng et al. teach a feed composition (column 2, lines 60-61), food compositions for humans (column 13, lines 2-3), liquid formulations (column 12, lines 32-40), and drinking water with a *Selenomonas ruminantum* phytase (column 12, lines 37-38). Cheng et al. teach the isolation of the *Selenomonas ruminantum* phytase, its amino acid sequence (SEQ ID NO: 2), the corresponding cDNA and its nucleic acid sequence (SEQ ID NO: 1). Cheng et al. teach production of the recombinant phytase in *E. coli* (gram-negative bacterial cell; Example 7), *Pichia pastoris* (eukaryotic fungal cell; Example 7), *B. napus* (plant cell; Example 7), vectors comprising the nucleic acid used for expression of the phytase (Example 7, columns 18-21), secretion of the phytase via a signal peptide (Example 7, column 19, lines 55-67; column 8, lines 51-57; column 9, lines 32-47), recombinant production of the phytase without a signal peptide (Example 7, column 18, line 63-column 19, line 54), recombinant production of the phytase in *Saccharomyces cerevisiae* cells (yeast cells; column 8, lines 40-45), *Bacillus subtilis* cells (gram-positive bacterial cells; column 8, lines 40-45), and *Aspergillus ficuum* cells (column 8, lines 40-45). Cheng et al. do not teach an E. coli phytase or a phytase containing food/feed composition comprising juice. Greiner et al. teach two *E. coli* phytases (Abstract; page 10, right column, Results, Purification of the phytases) and teach that phytases are of special interest in biotechnological

applications specially for the reduction of phytate in feedstuff and food (page 107, right column, last paragraph of Introduction). Greiner et al. does not teach the feed/food compositions of Cheng et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a feed/food composition, as taught by Cheng et al. with the phytases of Greiner et al. and further add juice. A person of ordinary skill in the art is motivated to make the claimed feed/food compositions with the *E. coli* phytases of Greiner et al. because Greiner et al. teach that phytases are of great interest specially for the reduction of phytate in food and feedstuff. Also, a person of ordinary skill in the art is motivated to add juice to the phytase containing food/feed composition to add flavor and some sweetness which would make the phytase composition more palatable. One of ordinary skill in the art has a reasonable expectation of success at making the feed/food compositions with the *E. coli* phytases since all that is required is replacing the phytases of Cheng et al. with those of Greiner et al. In addition, one of ordinary skill in the art has a reasonable expectation of success at adding juice to the phytase food/feed composition since this is an extremely common and easy to do step. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

35. Claims 8-13, 19, 24-31, 33-40, 50-53, 56-57, 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apajalahti et al. (GB 2316082 A, published 2/18/1998) in view of Greiner et al. (Archives of Biochemistry and Biophysics 303(1):107-113, 1993; cited in the IDS), and further in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). This rejection is necessitated by amendment and is now applied to claims 8-13, 19, 24-31, 33-40, 50-53, 56-57, 60-65 for the reasons of record and those set forth below.

36. With regard to claims 42-43, 45 and 47, Applicants submit that Apajalahti et al. is not proper prior art due to the priority date claimed.

37. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection of claims 8-13, 19, 24-31, 33-40, 50-53, 56-57, 60-65. For the reasons stated above, the claimed priority has not been granted.

Amended claims 8-13, 19, 26-31, 33-40, 50-52, 56, 60-65 of the instant application are directed in part to a feed/food composition comprising a phytase encoded by a nucleic acid derived from E. coli, wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Since how the phytase is made does not affect the structure or function of the phytase, no consideration has been placed on limitations regarding the method of making the phytase. Claim 23 is directed in part to a food composition for an animal comprising a phytase encoded by a nucleic acid derived from E. coli wherein said composition is a liquid formulation or comprises a liquid formulation. Claim 24 is directed to a drinkable foodstuff comprising a phytase encoded by a nucleic acid derived from E. coli. Claim 25 is directed in part to the drinkable foodstuff of claim 24 wherein the foodstuff further comprises juice. Claims 53 and 57 are directed to a food composition/drinkable foodstuff comprising a phytase encoded by a nucleic acid derived from E. coli wherein the phytase lacks a signal peptide.

Apajalahti et al. teach a food and feed composition comprising a *B. subtilis* phytase (page 10). Furthermore, Apajalahti et al. teach that the phytase can be added to the food/feed composition in liquid form (page 10). Apajalahti et al. teach the isolation of the *B. subtilis* phytase, its amino acid sequence (SEQ ID NO: 2), the corresponding cDNA and its nucleic acid sequence (SEQ ID NO: 1). Apajalahti et al. teach production of the recombinant phytase in *E. coli* without a signal peptide (Example 3), vectors comprising the nucleic acid used for expression of the phytase (Example 3), secretion of the phytase via a signal peptide (page 9, lines 3-10), recombinant production of the phytase in prokaryotic and eukaryotic host cells including yeast cells, bacterial cells, plant cells, fungal cells, *Saccharomyces* cells, *Pichia* cells, gram-positive cells, gram-negative cells, *E. coli* cells, *Bacillus subtilis* cells, *Lactobacillus* cells,

Lactococcus cells, and *Aspergillus* cells (page 9, lines 11-28). Apajalahti et al. do not teach an E. coli phytase or a liquid formulation comprising the phytase. The teachings of Cheng et al. have been discussed above. Cheng et al. teach a liquid formulation comprising a phytase but do not teach an E. coli phytase or a phytase containing food/feed composition comprising juice. Greiner et al. teach two *E. coli* phytases (Abstract; page 10, right column, Results, Purification of the phytases) and teach that phytases are of special interest in biotechnological applications specially for the reduction of phytate in feedstuff and food (page 107, right column, last paragraph of Introduction). Greiner et al. do not teach the feed/food compositions of Cheng et al. or Apajalahti et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a feed/food composition, as taught by Apajalahti et al., in liquid form, as taught by Chen et al. with the phytases of Greiner et al. and further add juice. A person of ordinary skill in the art is motivated to make the claimed feed/food compositions with the *E. coli* phytases of Greiner et al. because Greiner et al. teach that phytases are of great interest specially for the reduction of phytate in food and feedstuff. Also, a person of ordinary skill in the art is motivated to make a liquid composition to provide for an additional delivery method in case the target subject cannot chew, and add juice to provide flavor and some sweetness which would make the phytase composition more palatable. One of ordinary skill in the art has a reasonable expectation of success at making the feed/food compositions with the *E. coli* phytases since all that is required is replacing the phytase of Apajalahti et al. with those of Greiner et al. In addition, one of ordinary skill in the art has a reasonable expectation of success at adding juice to the phytase food/feed composition since this is an extremely common and easy to do step. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Double Patenting

38. Claims 8-14, 19-20, 23, 26-31, 33-41, 44 and 46 remain rejected and new claims 50-55, 60-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6110719. This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

39. Applicants have requested to hold this issue in abeyance until such time claims are held allowable.

40. In view of the fact that no arguments have been presented traversing the instant rejection and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record. It is noted that new claims 50-55, 60-66 encompass subject matter which has previously being indicated as being obvious over U.S. Patent No. 6110719. Also, it is noted that the instant patent also discloses a phytase without a signal peptide (column 9, lines 27-40).

41. Claims 21-22, 24-25, 48-49 remain rejected and new claims 56-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6110719 in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

42. Applicants have requested to hold this issue in abeyance until such time claims are held allowable.

43. In view of the fact that no arguments have been presented traversing the instant rejection and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record. It is noted that new claims 56-58 encompass subject matter which has previously being indicated as being obvious over

U.S. Patent No. 6110719 in view of Cheng et al. Also, it is noted that the instant patent also discloses a phytase without a signal peptide (column 9, lines 27-40).

44. Claims 8-14, 19-31, 33-41, 44, 46, 48-49 remain provisionally rejected and new claims 50-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 23-28, 30-31, 40-49 of copending Application No. 10/601319. This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

45. Applicants have requested to hold this issue in abeyance until such time claims are held allowable.

46. In view of the fact that no arguments have been presented traversing the instant rejection and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record. It is noted that new claims 50-66 encompass subject matter which has previously being indicated as being obvious over copending Application No. 10/601319. Also, it is noted that the instant copending application also discloses a phytase without a signal peptide (paragraph [140] of corresponding US publication).

47. Claims 8-14, 19-20, 23, 24, 26-31, 33-41, 44, 46, 48-49 remain provisionally rejected and new claims 50-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/933115. This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

48. Applicants have requested to hold this issue in abeyance until such time claims are held allowable.

49. In view of the fact that no arguments have been presented traversing the instant rejection and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record. It is noted that new claims 50-66 encompass subject matter which has previously being indicated as being obvious over

copending Application No. 10/933115. Also, it is noted that the instant copending application also discloses a phytase without a signal peptide (paragraph [149] of corresponding US publication).

50. Claims 8-14, 19-20, 23, 26-31, 33-41, 44, 46 remain provisionally rejected and new claims 50-55, 60-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 88-89, 96-103 of copending Application No. 11/056354. This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

51. Applicants have requested to hold this issue in abeyance until such time claims are held allowable.

52. In view of the fact that no arguments have been presented traversing the instant rejection and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record. It is noted that new claims 50-55, 60-66 encompass subject matter which has previously being indicated as being obvious over copending Application No. 11/056354. Also, it is noted that the instant copending application also discloses a phytase without a signal peptide (paragraphs [352]-[353] of corresponding US publication).

53. Claims 21-22, 24-25, 48-49 remain provisionally rejected and new claims 56-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 88-89, 96-103 of copending Application No. 11/056354 in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). This rejection has been discussed at length in the Non Final Action mailed on 5/18/2005.

54. In view of the fact that no arguments have been presented traversing the instant rejection and no terminal disclaimer has been filed, this rejection is maintained for the reasons of record. It is noted that new claims 56-58 encompass subject matter which has previously being indicated as being obvious over

copending Application No. 11/056354 in view of Cheng et al. Also, it is noted that the instant copending application also discloses a phytase without a signal peptide (paragraphs [352]-[353] of corresponding US publication).

Conclusion

55. No claim is in condition for allowance.

56. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

57. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

58. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

59. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
January 6, 2006

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600